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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,221	11/17/2003	Jonathan J. Langberg	MITRAL.001C2	5022
30452 7590 12/26/2007 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614			EXAMINER STEWART, JASON-DENNIS NEILKEN	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/715,221	Applicant(s) LANGBERG ET AL.	
	Examiner Jason-Dennis Stewart	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24, 25, 31-46 and 50 is/are pending in the application.
- 4a) Of the above claim(s) 25, 35, 39, 41 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 31-34, 36-38, 40, 42, 44-46 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>18 April 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a Final Office action in response to communications received September 4, 2007. Claims 1-23, 25-30, 35, 39, 41, 43, and 47-49 have been canceled. Claim 24 is amended. Claim 50 has been added. Claims 24, 31-34, 36-38, 40, 42, 44-46, and 50 are pending and addressed below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 24, 31-34, 36-38, 45, 46, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. 5,582,609 in view of Myers 5,716,397.

4. Regarding Claim 24, Swanson discloses a medical apparatus comprising: an elongate body 10 having a size capable for implantation at least within the coronary sinus (col. 1, ll. 30-38) movable between a first configuration for transluminal delivery and a second configuration (fig. 5, 6). It also discloses forming element 24 slidably contained within the body 10. Swanson also discloses an electrode. An electrode is merely an electrically conductive element. The electrodes disclosed in Swanson are capable of functioning as cardiac pacing electrodes if connected properly to a pulse generator or other source. "Cardiac pacing" is seen as an intended used limitation in

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this claim. However, Swanson does not disclose at least a portion of the forming element being removable after implantation.

Myers discloses an annuloplasty device with a forming element 28 that is removable upon implantation of the device in order to restore full flexibility to the device after implantation (col. 2, ll. 7-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Swanson with the removable forming element of Myers in order to restore full flexibility after the device is implanted as taught by Myers (col. 2, ll. 7-10).

5. Regarding Claim 31, Swanson illustrates the forming element 24 movable relative to the elongate body 10 (Fig. 5 and 6).

6. Regarding Claim 32, Swanson illustrates an arc configuration (Fig. 16A, 16B).

7. Regarding Claim 33, Swanson in view of Myers discloses the invention as claimed and as discussed above. However, Swanson in view of Myers does not positively recite the claimed range in Claim 33. However, it has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, **See MPEP 2144.05, Part II, Section A.**

8. Regarding Claims 34 and 36, Swanson discloses the invention as claimed and as discussed above. However, Swanson does not disclose a lock able to be engaged and disengaged.

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Myers discloses a security suture 62 used to prevent premature removal of the forming element 28 col. 4, ll. 10-15).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Swanson with the security suture of Myers in order to prevent premature removal of the forming element as taught by Myers (col. 4, ll. 10-15).

9. Regarding Claim 37, Swanson discloses a coating (col. 8, ll. 43-50).

10. Regarding Claim 38, Swanson discloses an apparatus movable from the implantation configuration to the remodeling configuration in response to proximal retraction of the forming element 24 (col. 5, ll. 53-55).

11. Regarding Claim 45, Swanson discloses a minimum diameter of the body being about 1.35 mm (col. 11, ll. 46-54).

12. Regarding Claim 50, Swanson discloses the invention as claimed and as discussed above. However, Swanson does not disclose only one forming element.

Myers illustrates only one forming element 28 (fig. 4) in order to maintain the device in its prescribed shape (col. 2, ll. 20-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Swanson with the singular forming element of Myers in order to maintain the device in its prescribed shape (col. 2, ll. 20-25).

13. Claims 40, 42, 44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. 5,582,609 in view of Myers 5,716,397 further in view of Goldsteen et al. 6,206,912.

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14. Regarding Claims 40, 42, and 46, Swanson in view of Myers discloses the invention as claimed and as discussed above. However, Swanson in view of Myers does not disclose an anchor.

Goldsteen discloses barbs 436 for the purpose of preventing the distal end of a conduit from being pulled proximally out of the coronary artery (col. 13, ll. 23-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the device of Swanson in view of Myers with the barbs of Goldsteen in order to prevent a conduit from being pulled proximally out of the coronary artery as taught by Goldsteen (col. 13, ll. 23-30).

15. Regarding Claim 44, Swanson discloses the flexible body being from about 4 french to about 10 french. Also, it has been held that "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, See MPEP 2144.05, Part II, Section A.

Response to Arguments

16. Applicant's arguments filed 09/04/2007 have been fully considered but they are not persuasive.

17. Applicant's arguments with respect to claims 24, 31-34, 36-38, 40, 42, 44-46, and 50 have been considered but are moot in view of the new ground(s) of rejection.

18. In response to applicant's argument that the electrodes of Swanson are not "cardiac pacing" electrodes, a recitation of the intended use of the claimed invention

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must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case. An electrode is merely an electrically conductive element. The electrodes disclosed in Swanson are capable of functioning as cardiac pacing electrodes if connected properly to a pulse generator or other source. "Cardiac pacing" is seen as an intended used limitation in this claim.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure, as per the Notice of References Cited.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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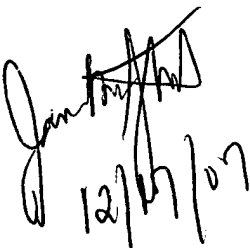
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason-Dennis Stewart whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS



12/17/07



BRIAN E. PELLEGRINO
PRIMARY EXAMINER